DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

MEDICARE DRUG BENEFIT AND C & D DATA GROUP

DATE: September 18, 2014

TO: Part D Sponsors

FROM: Amy K. Larrick
Acting Director, Medicare Drug Benefit and C & D Data Group

SUBJECT: Rescheduling of Hydrocodone Combination Products from Schedule III to Schedule II

On August 22, 2014, the DEA issued a final rule (79 FR 49661) in which they rescheduled hydrocodone combination products (HCPs) from schedule III to schedule II of the Controlled Substances Act as of October 6, 2014. Consequently, pursuant to the DEA's final rule, no HCP prescriptions issued on or after October 6, 2014 shall authorize any refills. However, the DEA rule states that any prescriptions for HCPs that are issued before October 6, 2014, and authorized for refilling, may be dispensed in accordance with 21 CFR 1306.22–1306.23, 1306.25, and 1306.27, if such dispensing occurs before April 8, 2015.

In order to minimize potential interruptions in therapy that could result from the rescheduling of HCPs, we urge sponsors to notify enrollees who have utilized HCPs in the past six months that they may experience a rejection at the point of sale for HCPs on or after October 6, 2014 in light of this change in prescription requirements. Sponsors could suggest that these beneficiaries may need to obtain new prescriptions for HCPs from their providers, written in accordance with the new rule. CMS does not require these ad hoc enrollee communication materials to be submitted to HPMS, but they must be maintained by the sponsor and made available to CMS upon request. CMS also plans to monitor complaint rates for concerns related to the transition of HCPs from schedule III to schedule II. However, we do not expect to take compliance actions related to this specific change if Part D sponsors' processes are consistent with the DEA final rule (79 FR 49661).

If you have any questions regarding this memorandum, please contact our Part D Policy mailbox at PartDPolicy@cms.hhs.gov.